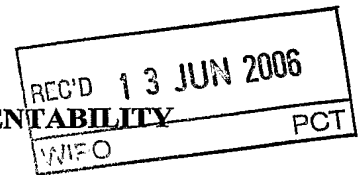


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference PU0406 - PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE2005/000292	International filing date (<i>day/month/year</i>) 24-02-2005	Priority date (<i>day/month/year</i>) 27-02-2004
International Patent Classification (IPC) or national classification and IPC See Supplemental Box		
Applicant GE HEALTHCARE BIO-SCIENCES AB et al		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.
3.	This report is also accompanied by ANNEXES, comprising: <div style="margin-left: 20px;"> <div style="margin-bottom: 10px;"> <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows: <div style="margin-left: 20px;"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. </div> </div> <div> <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). </div> </div>
4.	This report contains indications relating to the following items: <div style="margin-left: 20px;"> <div style="margin-bottom: 5px;"><input checked="" type="checkbox"/> Box No. I Basis of the report</div> <div style="margin-bottom: 5px;"><input type="checkbox"/> Box No. II Priority</div> <div style="margin-bottom: 5px;"><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</div> <div style="margin-bottom: 5px;"><input type="checkbox"/> Box No. IV Lack of unity of invention</div> <div style="margin-bottom: 5px;"><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</div> <div style="margin-bottom: 5px;"><input type="checkbox"/> Box No. VI Certain documents cited</div> <div style="margin-bottom: 5px;"><input type="checkbox"/> Box No. VII Certain defects in the international application</div> <div style="margin-bottom: 5px;"><input type="checkbox"/> Box No. VIII Certain observations on the international application</div> </div>

Date of submission of the demand 01-09-2005	Date of completion of this report 08-06-2006
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Patrick Andersson/EÖ Telephone No. +46 8 782 25 00

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2005/000292

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Cover sheet**

International patent classification (IPC)

B01J 39/04 (2006.01)

B01D 15/32 (2006.01)

B01D 15/36 (2006.01)

C07K 16/06 (2006.01)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2005/000292

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:



the international application in the language in which it was filed

a translation of the international application into _____,
which is the language of a translation furnished for the purposes of:

international search (Rules 12.3(a) and 23.1(b))



publication of the international application (Rule 12.4(a))



international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):



the international application as originally filed/furnished



the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



the claims:

pages _____ as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



the drawings:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:



the description, pages _____



the claims, Nos. _____



the drawings, sheets/figs _____

the sequence listing (*specify*): _____any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).



the description, pages _____



the claims, Nos. _____



the drawings, sheets/figs _____

the sequence listing (*specify*): _____any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2005/000292

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-3, 6-8</u>	YES
	Claims	<u>4-5, 9-12</u>	NO
Inventive step (IS)	Claims	<u> </u>	YES
	Claims	<u>1-12</u>	NO
Industrial applicability (IA)	Claims	<u>1-12</u>	YES
	Claims	<u> </u>	NO

2. Citations and explanations (Rule 70.7)

The following documents are considered relevant:

D1) Johansson B-L, "Preparation and characterization of prototypes for multimodal separation aimed for capture of positively charged biomolecules at high-salt conditions", 2003, vol 1016 page 35-49 Journal of Chromatography A.

D2) WO9710887

D3) EP0345649

D1 and D2 disclose a process for purifying antibodies using a multi-modal separation material which is a cation-exchange resin with aromatic ring systems where the ring-forming atoms can be carbon, sulphur or oxygen, see e.g. table 2, figure 3 of D1.

In D1, it is stated that the resin should be tested for capture proteins from different feedstocks.

Consequently, the subject matter of claims 1-3 and 6-8 is previously known and lacks novelty.

Document D2 is considered to represent the closest prior art. The invention according to claims 4-5 and 9-12 differs from the process in D2 in that the solution from a previous protein-A purification step uses a chromatographic resin with a multimodal ligand.

Consequently, with the background of D2, the problem solved by the present application is to design an alternative process to purify antibodies.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

The problem with leakage from protein-A columns is well known in the art. Moreover, it is common to combine protein-A chromatography with other chromatographic steps.

To solve the problem in D2 using another chromatographic step known to be used for antibody purification, such as the one in D1, seems to be obvious to a person skilled in the art in the absence of an unforeseeable advantage with the method used. Consequently, the invention according to claims 4-5 and 9-12 lacks an inventive step.

Claims 1-12 are considered industrially applicable.